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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,841	08/31/2005	Alexander Gaiger	210121.49402USPC	9134

500 7590 10/14/2009

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
10/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,841	GAIGER ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,21-28,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,21-28,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 18-20, 29-31 and 34-53 are canceled. Claims 17, 21-28, 32 and 33 are amended and under consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 17, 21-28, 32 and 33 under 35 U.S.C. 102(e) as being anticipated by Kindsvogel (WO 2002066516) is maintained for reasons of record.

Claim 17 is drawn to a method for treating CLL in a mammalian subject comprising administration of an effective amount of an isolated monoclonal antibody that specifically binds to a polypeptide comprising the sequence of SEQ ID NO:4. Claims 21-25 embody the method of claim 17 wherein the antibody is humanized, chimeric, a Fab fragment, a Fv fragment, and a scFv, respectively. Claim 26 specifies that the antibody of claim 17 further comprises a therapeutic moiety. Claim 27 specifies that the therapeutic moiety is a radionuclide and claim 28 requires that the radionuclide be selected from a group including ^{131}I. Claim 32 embodies the method of claim 17 wherein the subject is human. Claim 33 embodies the method of claim 17, wherein the administration is intravenous.

Claims 34-38 are drawn to a method comprising the steps of (a)contacting a biological sample from a patient with a monoclonal antibody that specifically binds to SEQ ID NO:4 and detecting the complex formed between the monoclonal antibody and SEQ ID NO:4.

Claim 39 is drawn to an isolated monoclonal antibody that specifically binds SEQ ID NO:4. Claims 43-47 embody the isolated antibody of claim 39 wherein said antibody is

humanized, chimeric, a Fab fragment, a Fv fragment and a scFv, respectively. Claim 48 embodies the antibody of claim 39 further comprising a reporter group. Claim 49 embodies the antibody of claim 39 further comprising a therapeutic moiety. Claim 50 specifies that the therapeutic moiety is a radionuclide. Claim 51 further specifies that the radionuclide is selected from a group including 131I. Claim 52 is drawn to a kit comprising a monoclonal antibody that specifically binds SEQ ID NO:4 and instructions for use.

Claim 42 is drawn to a pharmaceutical composition comprising the monoclonal antibody of claim 39 and a pharmaceutically acceptable carrier.

Kindsvogel discloses a monoclonal antibodies that bind to BCMA (page 23, line 27 to page 24, line 33 and page 53 Table I) and bi-specific antibody that binds to BCMA (pages 15-16 under the heading of "Production of anti-BCMA-TACI Antibodies"), wherein the sequence of BCMA (Sequence Identifier 2) is identical to the instant SEQ ID NO:4:

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   WO200266516-A2.
XX
PD   29-AUG-2002.
XX
PF   06-FEB-2002; 2002WO-US003500.
XX
PR   20-FEB-2001; 2001US-0270274P.
PR   12-APR-2001; 2001US-0283447P.
XX
PA   (ZYMO ) ZYMOGENETICS INC.
XX
PI   Kindsvogel W;
XX
DR   WPI; 2002-723183/78.
DR   N-PSDB; AAD46410.
DR   PC:NCBI; gi399104.
DR   PC:SWISSPROT; Q02223.
XX
PT   B-cell maturation antigen and transmembrane activator and calcium-
PT   modulator and cyclophilin ligand-interactor, useful for treating
PT   disorders e.g. inflammation or lymphoma.
XX
PS   Disclosure; Page 63; 67pp; English.
XX
CC   The invention relates to the manufacture of a composition for inhibiting
CC   the proliferation of tumour cells. The method involves using an antibody
CC   component that binds both the B-cell maturation antigen (BCMA) and the
CC   transmembrane activator and calcium-modulator and cyclophilin ligand-
CC   interactor (TACI). BCMA and TACI binding antibody compositions are useful
CC   for inhibiting proliferation of tumour cells, particularly inhibiting
CC   2TNF4 activity in a mammal associated with increased endogenous antibody
CC   production or a disorder consisting of neoplasm, chronic lymphocytic
CC   leukaemia, multiple myeloma, non-Hodgkin's lymphoma, post-transplantation
CC   lymphoproliferative disease or light chain gammopathy or inflammation
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CC   e.g. asthma. The invention is also useful in gene therapy. The present is
CC   human BCMA protein
CC
SQ   Sequence 184 AA;

  Query Match           100.0%;  Score 964;  DB 5;  Length 184;
  Best Local Similarity  100.0%;  Pred. No. 2.5e-94;
  Matches  184;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MLQMAGQCSQNEYFDSLLHACIPCQLRCSSNTPPLTCQRYCNASVTNSVKGTNAILWTCL 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MLQMAGQCSQNEYFDSLLHACIPCQLRCSSNTPPLTCQRYCNASVTNSVKGTNAILWTCL 60

Qy         61 GLSLIISLAVFVLMFLLRKISSEPLKDEFKNTGSGLLGMANIDLEKSRTGDEILPRGLE 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 GLSLIISLAVFVLMFLLRKISSEPLKDEFKNTGSGLLGMANIDLEKSRTGDEILPRGLE 120

Qy        121 YTVEECTCEDCIKSKPKVDSDHCFPLPAMEEGATILVTTKTNDYCKSLPAALSATEIEKS 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 YTVEECTCEDCIKSKPKVDSDHCFPLPAMEEGATILVTTKTNDYCKSLPAALSATEIEKS 180

Qy        181 ISAR 184
              ||||
Db        181 ISAR 184
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Kindsvogel discloses that the bi-specific antibody is useful in the treatment of B lymphomas and chronic lymphocytic leukemia (page 6, lines 13-19) which is the same as that disclosed in the instant specification (page 24, section [181])and originally filed claims (claim 16). Kindsvogel discloses that the bi-specific antibody further comprises a therapeutic moiety (page37, lines 14-37, page 38, lines 1-2 and page 49, lines 3-4) which includes ^{90}Y, ^{123}I,^{131}I, and ^{186}Re (page 37, lines 6-14). Kindsvogel discloses that the antibodies encompass humanized, chimeric Fab or scFv fragments (page 4, lines 17-22). Kindsvogel discloses pharmaceutical compositions comprising the antibodies (page 43, lines 13-35) and the administered via an intravenous route (page 42, line 35). Kindsvogel discloses kits comprising the anti-BCMA-TACI antibody or fragments with a "means for conveying to the user" that the antibody or fragments are used to detect BCMA or TACI proteins (page 32, lines 1-12) which meets the limitation of claim 52.

Applicant argues that the bi-specific antibody of Kindsvogel does not meet the requirement of specifically-binding as set forth in the instant specification which states on page 26, (paragraph 189) that the antibody reacts does not react at a detectable level with unrelated

peptides or proteins. This has been considered but not found persuasive. The anti-BCMA portion of the bi-specific antibody of Kindsvogel specifically binds BCMA, and the anti-TACI portion of the bi-specific antibody of Kindsvogel specifically binds TACI. The quotation from the instant specification is taken from a paragraph explaining what is meant by the words "specifically bind". One of skill in the art would not conclude based on reading the instant disclosure that the definition applied to "specifically bind" excludes bi-specific antibodies that specifically bind two different target epitopes because each of the antibodies of the bi-specific antibody "specifically bind" to their target epitope. Further, the instant specification discloses bi-specific antibodies as part of the invention (page 24, section [181])and originally filed claims (claim 16).

All claims are rejected.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicant's amendments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/
Primary Examiner, Art Unit 1643